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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 09/641,471 | 08/18/2000 | Carol M. Kinoshita | 10278-017001 | 6615 |
| 26161 | 7590 | 04/09/2004 | EXAMINER | |
| FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110 | | | SLOBODYANSKY, ELIZABETH | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1652 | |

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/641,471

Applicant(s)

KINOSHITA ET AL.

Examiner

Elizabeth Slobodyansky, PhD

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 18 March 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): 112, 2nd, of claims 144-147.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 105,106,109-131,133-142,144-164,167-171,184 and 185.

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____



Elizabeth Slobodyansky, PhD
Primary Examiner
Art Unit: 1652

Continuation of 5. does NOT place the application in condition for allowance because: Applicants argue with regard to the 103(a) rejection that "in view of Smith, Applicants' results showing that GCB harvested from kifunensine treated cells showed a 400% increase in function (e.g., uptake) is indeed unexpected. Accordingly, even if a prima facie case of obviousness had been made (which Applicants do not concede), Applicants' unexpected results are sufficient to overcome it" (Remarks, page 17). This is not persuasive because the unexpected results must be commensurate in scope with the claims. Applicants refer to US 5,641,670 to describe the glucocerebrosidase gene activation. However, there is no description in said patent of the glucocerebrosidase gene activation. To overcome the 103 rejection Applicants must describe the mammalian cell expressing GCB that when contacted with kifunensine produces unexpected results. This would include the description of the regulatory sequence, for example, that has been used to activate the GCB gene. Claims 167-169 would be rejected under 112, 2nd, as dependent from canceled claim 166.